



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-609; NRC-2013-0235]

Medical Radioisotope Production Facility; Northwest Medical Isotopes, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: Construction permit application; opportunity to request a hearing and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is providing notice of an uncontested hearing and an opportunity to request a hearing on the Northwest Medical Isotopes, LLC (NWMI), construction permit application that proposes the construction of a medical radioisotope production facility in Columbia, Missouri. The NRC staff is currently conducting a detailed technical review of the construction permit application. If the NRC issues a construction permit, the applicant, NWMI, would be authorized to construct its proposed production facility in accordance with the provisions of the construction permit. The application contains sensitive unclassified non-safeguards information (SUNSI).

DATES: A request for a hearing must be filed by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by **[INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID **NRC-2013-0235** when contacting the NRC about the availability of information regarding this document.

You may obtain publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2013-0235**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Michael Balazik, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone:

301-415-2856, e-mail: Michael.Balazik@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

By letters dated February 5, 2015 (ADAMS Accession No. ML15086A261), and July 20, 2015 (ADAMS Accession No. ML15210A182), NWMI submitted a construction permit application that proposed to construct a medical radioisotope production facility. The notice accepting part one of the application for docketing was published on June 8, 2015 (80 FR 32418). The notice accepting the second and final portion of NWMI's two-part construction permit application for docketing was published on January 4, 2016 (81 FR 101). The docket number established for this application is 50-609.

The NRC is considering issuance of a construction permit to NWMI that would authorize construction of the NWMI proposed production facility as defined by 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities," to be located in Columbia, Missouri.

II. Uncontested Hearing

Pursuant to the Atomic Energy Act of 1954, as amended (the Act), and 10 CFR parts 2 and 50, "Agency Rules of Practice and Procedure" and "Domestic Licensing of Production and Utilization Facilities," respectively, notice is hereby given that an uncontested (i.e., mandatory) hearing will be held at a time and place to be set in the future by the Commission.

The uncontested hearing on the application for a construction permit filed by NWMI

pursuant to 10 CFR part 50 will be conducted by the Commission. The NRC staff will complete a detailed technical review of the application and will document its findings in a safety evaluation report. The Commission will refer a copy of the application to the Advisory Committee on Reactor Safeguards (ACRS) in accordance with 10 CFR 50.58, "Hearings and Report of the Advisory Committee on Reactor Safeguards," and the ACRS will report on those portions of the application that concern safety. The NRC staff will also complete an environmental review of the application and will document its findings in an environmental impact statement in accordance with the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

III. Opportunity to Request a Hearing and Petition for Leave to Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition for leave to intervene with respect to issuance of the construction permit application. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure," in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board

Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) the name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the construction permit application under consideration. The contention must be one which, if

proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies and procedures.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)-(iii).

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental

body, Federally-recognized Indian Tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at

hearing.docket@nrc.gov, or by telephone at 301-415-1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene.

Submissions should be in Portable Document Format in accordance with NRC guidance available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001,

Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff.

Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

**V. Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards
Information for Contention Preparation**

Northwest Medical Isotopes, LLC, Docket No. 50-609, Columbia, Missouri

- A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.
- B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A “potential party” is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.
- C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555-0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The e-mail address for the Office of the Secretary and the Office of the General Counsel are Hearing.Docket@nrc.gov and OGCmailcenter@nrc.gov, respectively.¹ The request must include the following information:

¹ While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC’s “E-Filing Rule,” the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

- (1) A description of the licensing action with a citation to this *Federal Register* notice;
- (2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and
- (3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

- (1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and
- (2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order² setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the

² Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

requestor no later than 25 days after the requestor is provided access to that information. However, if more than 25 days remain between the dates the petitioner is provided access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) an officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of

interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.³

³ Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

IT IS SO ORDERED.

Dated at Rockville, Maryland, this 18th day of May, 2016.

For the Nuclear Regulatory Commission.

Rochelle C. Bovol, Acting,
Secretary of the Commission.

ATTACHMENT 1--General Target Schedule for Processing and Resolving Requests for Access to Sensitive Unclassified Non-Safeguards Information in this Proceeding

Day	Event/Activity
0	Publication of <i>Federal Register</i> notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no "need" or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.

Day	Event/Activity
A	If access granted: issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.